IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEIJER, INC. and MEIJER DISTRIBUTION, INC., on behalf of itself and all others similarly situated,	)	
Plaintiff,	)	C.A. No.
v.	)	
BRAINTREE LABORATORIES, INC.,	)	JURY TRIAL DEMANDED
Defendant.	)	

CLASS ACTION COMPLAINT

Plaintiffs, on behalf of themselves and the class defined below, brings this antitrust action against Defendant Braintree Laboratories, Inc. ("Braintree" or "Defendant") and allege as follows based upon personal knowledge as to matters relating to itself and upon the investigation of its counsel and information and belief as to all other matters:

NATURE OF THE CASE

1. This case arises from Braintree's anticompetitive scheme to block entry of generic competition in order to maintain its monopoly power in the United States over MiraLax (polyethylene glycol 3350) and any actual or potential A-rated generic competitors. Braintree's scheme was intended to, and succeeded in, allowing it to charge supracompetitive prices for polyethylene glycol 3350, causing Plaintiffs and members of the class to pay overcharges on their purchases.

2. Braintree sells polyethylene glycol 3350 in the United States under the brand name MiraLax. MiraLax is an osmotic laxative that causes water to be retained in the stool. MiraLax was

approved by the United States Food & Drug Administration ("FDA") in February 1999 for the treatment of occasional constipation.

3. As alleged in greater detail herein, Braintree engaged in a scheme involving U.S. Patent No. 5,710,183 (the "'183 patent") issued by the United States Patent and Trademark Office ("PTO"). This misconduct involved, *inter alia*, the improper listing of the '183 patent with the FDA, and improperly asserting infringement claims based on the '183 patent.

4. Braintree proceeded improperly to procure the listing of the '183 patent with the FDA, in order to position itself to enforce the patent by filing patent infringement claims against any potential competitor seeking FDA approval to manufacture and sell a competing, generic version of MiraLax. Braintree knew that the mere filing of such patent infringement claims would block the market entry of potential competitors, irrespective of the merits of the claims.

5. Braintree then instituted a baseless lawsuit against a potential competitor for the purpose of forestalling generic competition. In May 2003, Braintree filed a patent infringement lawsuit against Schwarz Pharma Manufacturing, Inc. ("SPMI"), a company seeking FDA approval to market a generic version of MiraLax, even though Braintree knew that the '183 patent was improperly procured and that no reasonable claim of infringement could be based upon it.

6. Braintree filed this lawsuit not for any legitimate purpose, but because it knew that the mere filing of such litigation would raise barriers to the entry of generic competition, including automatically delaying the FDA's granting of final marketing approval to SPMI's generic version of MiraLax. Without such approval, generic manufacturers cannot bring their products to market.

7. By its unlawful acts, Braintree has willfully and unlawfully maintained its monopoly power over MiraLax and generic and bioequivalent forms of the drug.

8. Braintree's anticompetitive scheme was successful for a time in protecting its revenues from MiraLax from generic competition.

9. Through its illegal conduct, Braintree unlawfully deprived Plaintiffs (and other direct purchasers who comprise the class defined below) of access to substantially lower-priced generic versions of MiraLax. Braintree has caused Plaintiffs and the class to overpay for polyethylene glycol 3350 by many millions of dollars.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this civil action pursuant to 28 U.S.C. §§ 1331 and 1337.

11. Venue is proper in this District under 28 U.S.C. § 1391 and 15 U.S.C. §§ 15(a) and/or 15 U.S.C. § 22 because Defendant transacts business, committed an illegal or tortious act, has an agent, and/or is found within this District, and/or because a substantial portion of the events described below have been carried out in this District.

PARTIES

12. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer") are corporations organized under the laws of the State of Michigan, with their principal place of business in Grand Rapids, Michigan. Meijer is the assignee of the claims of the Frank W. Kerr Co., which, during the class period, as defined below, purchased MiraLax directly from Braintree.

13. Defendant Braintree Laboratories, Inc. is a privately held corporation organized and existing under the laws of the Commonwealth of Massachusetts, having its principal place of business at 60 Columbian Street West, Braintree, Massachusetts 02185-0929.

INTERSTATE AND COMMERCE

14. During all or part of the class period (defined below), Defendant manufactured and sold substantial amounts of MiraLax in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

15. At all material times, MiraLax was manufactured and sold by Defendant and was shipped across state lines and sold to customers located outside its state of manufacture.

16. During all or part of the class period, Defendant transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of MiraLax.

17. In furtherance of its efforts willfully to obtain and/or maintain monopoly power over MiraLax and its generic equivalents, Defendant employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

18. Defendant's efforts willfully to obtain and/or maintain monopoly power over MiraLax and its generic equivalents, as alleged herein, has substantially affected interstate and foreign commerce.

CLASS ALLEGATIONS

19. Plaintiffs bring this action under Rule 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of themselves and the following class (the "Class"):

> All persons and entities in the United States who purchased MiraLax directly from Defendant Braintree Laboratories, Inc. at any time from December 23, 2003, until the effects of Defendant's anticompetitive conduct cease (the "Class Period"). Excluded from the Class are Defendant and its parents, employees, subsidiaries, and affiliates.

20. The Class is so numerous that joinder of all members is impracticable. Plaintiffs believe that the Class numbers one hundred or more.

21. There are questions of law or fact common to the Class, including:

a. whether Braintree willfully obtained and/or maintained monopoly power over polyethylene glycol 3350 and its actual or potential generic equivalents;

b. whether the '183 patent was issued erroneously;

c. whether Braintree's lawsuit asserting infringement of the '183 patent was baseless;

d. whether Braintree filed such lawsuit for the purpose of preventing or delaying competition; and

e. whether, and to what extent, Braintree's conduct caused direct purchasers of MiraLax to be overcharged and therefore injured.

22. These and other questions of law and fact are common to the members of Class and predominate over any questions affecting only individual members.

23. Plaintiffs' claims are typical of the claims of the Class because all Class members suffered antitrust injury in the same way as a result of Defendant's wrongdoing, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

24. Plaintiffs will fairly and adequately represent and protect the interest of the Class. Plaintiffs have retained counsel experienced in class action and pharmaceutical antitrust litigation, and Plaintiffs have no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

25. A class action is superior to any other available methods for the fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty that will be encountered in the management of the claims advanced by the Class that would preclude class certification.

BACKGROUND

Federal Regulation of Prescription Drugs

A. Brand-Name Drugs vs. Generic Drugs

26. The brand-name prescription drugs industry is one of the most profitable industries in the United States. Over $250 billion was spent on prescription drugs in the United States in 2005, with $229.5 billion spent on brand-name drugs. The cost of prescription drugs has been rising at a rate of 14% to 18% per year.

27. Securing the availability of generic drugs is one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which must be approved by the FDA, by law have the same active chemical composition and provide the same therapeutic effects as the brand-name drugs to which they correspond.

28. The FDA will assign an "A" rating to generic drugs that are bioequivalent to pioneer or brand-name drugs. To be deemed a therapeutic equivalent, and assigned an "A" rating by the FDA, the generic drug must contain the same active ingredient(s), dosage form, route of administration, and strength. According to the FDA, a bioequivalent drug rated "A" may be substituted for the reference pioneer or branded drug.

29. Once the safety and effectiveness of a new prescription drug is approved by the FDA, the drug may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be purchased from a licensed pharmacist.

The pharmacist, in turn, must fill the prescription with the drug brand specified by the physician, unless an A-rated generic version of that pioneer drug approved by the FDA is available.

30. If a generic version of a brand-name drug exists and the physician has not specifically indicated to the pharmacist to dispense the branded drug then: (i) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug, and (ii) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the option of purchasing the branded drug or the A-rated generic drug at a lower price.

31. Once a physician writes a prescription for a brand-name drug such as MiraLax, that prescription defines and limits the market to the drug name or it's A-rated generic equivalents. Only drugs that are A-rated by the FDA may be substituted by a pharmacist for a physician's prescription for the brand-name drug.

32. Generic drugs are priced substantially below the brand-name drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budge Office ("CBO") concluded that generic drugs save purchasers between $8 billion and $10 billion a year.

33. The Federal Trade Commission ("FTC") estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the brand-name drug. As additional manufactures bring generic versions of the drug to market, the price continues to drop.

34. A brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition. The 1998 CBO study estimated that, at that time, generic drugs captured at least 44% of the brand-name drug's market share in just the first year of sale.

B. Federal Scheme for Approval of Pioneer Drugs

35. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* (The "FD&C Act") regulates the manufacture and distribution of drugs and medical devices in the United States. Under the FD&C Act, approval by the FDA (the governmental body charged with the regulation of the pharmaceutical industry) is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 335(a). Premarket approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 335(b) of the FD&C Act, demonstrating that the drug is safe and effective for its intended use.

36. New drugs that are approved for sale in the United States by the FDA are often covered by patents, which provide the patent owner with the ability to seek to exclude others from making, using, and/or selling (depending on the scope of the patent) that new drug in the United States for the duration of the patent, plus any extension of the original patent granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("Hatch-Waxman Act").

37. Pursuant to 21 U.S.C. § 335(b), in its NDA, the pioneer drug manufacturer must list those patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. Once the NDA is approved by the FDA, any such patents are listed with the NDA in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

38. Federal regulations impose strict limitations on the types of the patents that an NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits NDA holders

from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

39. Despite the FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has regrettably become common for brand-name pharmaceutical companies to list in the Orange Book any and every patent they can obtain, in order to force generic manufactures to file what, as described below, is commonly known as a Paragraph IV Certification.

40. The FDA does not police the listing of patents. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing in the Orange Book. The FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information . . . .").

41. The FDA's role in the patent listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder submitting the patent for listing.

C. Approval of Generic Drugs

42. Congress enacted the Hatch-Waxman Act in 1984. The Hatch-Waxman Act was principally designed to streamline the process by which generic drugs are brought to market. The Hatch-Waxman Act simplified the regulatory hurdles faced by prospective generic drug manufactures by eliminating the need for such manufactures to file lengthy and costly NDAs. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand-name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA"), pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand-name drug.

43. Under the Hatch-Waxman Act, a generic drug manufacturer's ANDA must contain one of four certifications pursuant to 21U.S.C. § 355(j)(2)(A)(vii) addressing the patents, if any, listed in the Orange Book as applying to the brand-name or pioneer drug. Four types of certifications are available:

I. The brand name manufacture has not filed patent information with the FDA (a "Paragraph I Certification");

II. The patent or patents listed in the Orange Book have expired (a "Paragraph II Certification");

III. The patent or patents listed in the Orange Book will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a "Paragraph III Certification"); or

IV. The patent or patents listed in the Orange Book are invalid or not infringed by the generic manufacturer's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii).

44. If a generic manufacturer files a Paragraph IV Certification, seeking to market the generic drug before patent expiration and asserting that any listed patent is invalid or will not be infringed, the brand-name manufacturer has the opportunity to delay the generic manufacturer's receipt of final FDA approval, and, thus, its ability to come to market. This is because a generic manufacturer filing a Paragraph IV Certification must promptly give notice of this fact to both the NDA owner and the owner of the patent(s) at issue, and this certification constitutes a "technical act of infringement" under the Hatch-Waxman Act.

45. The filing of a Paragraph IV Certification thus creates jurisdiction in the federal courts to entertain a patent infringement action, and gives the NDA holder forty-five days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, the FDA's approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

46. Because of this thirty-month stay of ANDA approval, the mere filing of an infringement action in response to a Paragraph IV Certification, regardless of the action's underlying merit, gives the brand-name company the equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without requiring the brand company to establish likelihood of success on the merits, irreparable harm, that the balance of hardships tips in its favor, or that the public good is served by the blocking of entry.

47. As a practical matter the brand name company wins the lawsuit simply by filing it, as it automatically protects its monopoly for up to two-and-a-half years while the infringement action winds its way through the court system. Moreover, the brand name company has an incentive to stall the progress of the litigation. There are no disgorgement provisions for profits earned during the thirty-month period of exclusivity if a court eventually determines that the suit was without merit.

48. An improper Orange Book listing also has additional anticompetitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of marketing exclusivity in relation to other generic manufactures. 21 U.S.C. § 355(j)(5)(B)(iv). Absent an improper Orange Book listing, no Paragraph IV Certification would be required and, thus, no generic company would receive any 180-day exclusivity; rather, multiple generic competitors would enter the market simultaneously, resulting in prices even lower

than one would find during the 180-day exclusivity period when only one generic manufacturer is permitted to market its product.

49. Defendant was at all times fully familiar with the ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Amendments.

BRAINTREE'S ANTICOMPETITIVE CONDUCT

50. Braintree successfully forestalled generic competition to MiraLax from entering the market, thereby depriving purchasers of the benefits of cheaper polyethylene glycol 3350 products, by improperly listing the '183 patent in the Orange Book, and by bringing a patent infringement lawsuit based on the '183 patent.

A. The '183 Patent Approval, Acquisition by Braintree, and Listing in the Orange Book

51. Braintree has asserted that the '183 patent covers MiraLax and bars generic competition. The '183 patent claims, *inter alia*, a composition for the improvement of bowel function comprising polyethylene glycol and a fiber bulking agent, wherein the polyethylene glycol is present in a weight ratio of polyethylene glycol to fiber of at least about 1:2 and no more than about 7:1.

52. The patent application was filed on July 14, 1995. George M. Halow of El Paso, Texas was listed as the inventor.

53. During the prosecution of the '183 patent, the Examiner issued an Office Action dated February 25, 1997, rejecting claims 1-33 in the '183 patent. The Examiner found that the combination of several references–Kais, Powell, Parker/Kimura, and Fordtran–teach polyethylene glycol with a fiber bulking agent.

54. Claim 34, which ultimately issued as claim 33, claims "a method for improving bowel function in a mammal, comprising orally administering polyethylene glycol to the mammal in an amount sufficient to improve bowel motility, stool formation or both." Claim 34 (issued as claim 33) makes no reference to use of a fiber bulking agent.

55. The Examiner separately rejected claim 34 as obvious in light of Kimura or Fordtran, as both references teach compositions containing polyethylene glycol to improve bowel movement.

56. Halow, and/or individuals acting on his behalf, represented to the PTO in a response dated May 27, 1997, that claims 1-34 "provide a unique composition containing polyethylene glycol and a fiber bulking agent wherein PEG is present in a weight ratio of polyethylene glycol to fiber of from about 1 to 2 to no more than about 7 to 1. These percentages are critical and nowhere are they discussed or taught in the base references or the alleged equivalence teaching set forth by the secondary references."

57. Additionally, Halow and/or individuals acting on his behalf emphasized in the response the critical nature of the ratio of polyethylene glycol and fiber by explaining that if "the PEG to fiber ratio is too low, rapid onset of activity of the products of the invention drops off and begins to approach the low onset of a fiber based bulk laxative of the prior art. If the PEG to fiber ratio is too high, the volume of composition which must be ingested to obtain the benefits of the fiber content may be too high and the excess PEG may result in undesirable effects, such as those associated with PEG based bowel lavage compositions, such as those set forth in Kimura, et al or Fordtran."

58. The Examiner issued a Notice of Allowance reasoning that "the claims are considered to distinguish over the prior art since there is no teaching of the ratio for the two active ingredients."

59. The '183 patent was issued on January 20, 1998.

60. Crucially, 32 of the 33 claims in the '183 patent were limited by the ratio for the two active ingredients. Claims 33, however, issued unchanged and without this restriction, despite having been rejected by the PTO because it was prior art.

61. On information and belief, Braintree had previously, in approximately 1985 and 1990, sought to patent polyethylene glycol 3350, but each time the PTO rejected Braintree's patent application because it was based on prior art.

62. On information and belief, when Braintree filed its NDA for MiraLax, Braintree owned no patents that covered MiraLax.

63. On information and belief, Braintree learned about the '183 patent while its NDA for MiraLax was pending.

64. On information and belief, Braintree's counsel examined the '183 patent issued to Halow and concluded, in a December 23, 1998 letter sent to Halow, that claim 33 of the '183 patent was directly anticipated by the prior art, and hence invalid.

65. On information and belief, Braintree paid Halow a nuisance-value payment of approximately $15,000 for a non-exclusive license of the '183 patent.

66. On information and belief, Braintree nevertheless listed the '183 patent in the FDA's Orange Book in 1999, the same year that Braintree received final marketing approval for its MiraLax NDA and began selling MiraLax.

67. On information and belief, Braintree did not purchase the '183 patent outright from Halow until late 2001, shortly before MiraLax would lose its marketing exclusivity on February 18, 2002.

B. Braintree's Filing of a Sham Lawsuit

68. On January 30, 2003, SPMI submitted an ANDA with the FDA for a generic version of Braintree's MiraLax. SPMI called its generic product GlycoLax. SPMI's GlycoLax is comprised of only polyethylene glycol and does not contain a fiber bulking agent.

69. In accordance with 21 U.S.C. § 355(j)(5)(B), SPMI sent Braintree a Paragraph IV certification letter on April 1, 2003.

70. On May 16, 2003, Braintree filed suit against SPMI for infringement of claim 33 of the '183 patent in the United States Court for the District of Delaware, thereby invoking the Hatch-Waxman Act's automatic 30-month stay. Braintree sued for patent infringement only as to claim 33.

71. On September 3, 2003–more than three months after it filed the action–Braintree finally served a complaint on SPMI.

72. Braintree knew or should have known that its claims against SPMI were baseless. Specifically, Braintree knew or should have known: (a) that the Examiner's objections to the claims issued in the '183 patent were only overcome by representations from Halow and/or persons acting on his behalf that it was the ratio of polyethylene glycol to the fiber bulking agent that was "critical" to the patent application and such ratio was not taught or otherwise rendered obvious by the prior art; (b) the claims of the '183 patent, if read to cover pure polyethylene glycol compositions, calls into question the *bona fides* upon which the patent was issued; (c) if construed to cover polyethylene glycol alone, claim 33 is invalid in view of prior art; (d) if construed to cover polyethylene glycol alone, there were public uses of the patented subject matter outside the one year grace period set forth in 35 U.S.C. § 102(b); (e) if construed to cover polyethylene glycol alone, there was no disclosure of polyethylene glycol only compositions, or their preparation or application, in

accordance with the requirements of 35 U.S.C. § 112; and (f) if construed to cover polyethylene glycol alone, the use of compositions comprising polyethylene glycol to treat constipation was known for twenty years prior to the filing of the Halow application on July 14, 1995. Alternatively, Braintree knew or should have known that claim 33 cannot be construed to cover the use of polyethylene glycol alone and that SPMI's GlycoLax is comprised of only polyethylene glycol. GlycoLax does not contain a fiber bulking agent.

73. On December 23, 2003, SPMI received a tentative approval letter from the FDA for its ANDA for GlycoLax. This approval would have become final but for Braintree's baseless lawsuit claiming that SPMI infringed claim 33 of the '183 patent. Indeed, as discussed below, Braintree's baseless lawsuit delayed even tentative approval. Absent such conduct, SPMI's generic version of Miralax would have been approved and on the market much earlier.

74. On May 21, 2004, Braintree wrote to SPMI that it had decided to voluntarily dismiss its patent infringement claim against SPMI with prejudice and without costs. Braintree also offered SPMI a royalty-free license to claim 33 of the '183 patent.

75. On May 24, 2004, Braintree filed "Plaintiff's Motion for Voluntary Dismissal of Its Complaint and Motion to Dismiss Defendant's First Counter Claim as Moot."

76. On June 3, 2004, the Court dismissed Braintree's complaint with prejudice, ending the remaining portion of the thirty month stay of SPMI's ANDA approval.

77. Less than one month later, on July 2, 2004 the FDA gave final approval of SPMI's ANDA for its GlycoLax product. Within days of the FDA's final approval, GlycoLax was shipped to customers in the United States.

EFFECTS ON COMPETITION

78. Braintree's exclusionary conduct has delayed generic competition to MiraLax and enabled Braintree to sell MiraLax without generic competition. But for Braintree's misconduct, one or more competitors would have begun marketing A-rated generic versions of MiraLax much sooner than such versions actually were marketed, and Braintree itself would have entered the market with its own generic version of MiraLax..

79. Braintree's unlawful conduct caused the ANDA approval process to be delayed by the FDA and caused SPMI to divert its resources from its ANDA application and to expend substantial resources on litigation. Absent the patent lawsuit, SPMI and the FDA would have had reason to, and would have, focused and directed their limited resources into the ANDA approval process for generic polyethylene glycol 3350. Such focus and resources would have brought earlier FDA approval and marketing of generic polyethylene glycol 3350. However, Braintree's baseless suit–because it triggered the Hatch-Waxman Act's automatic 30-month stay that would block marketing regardless of approval–destroyed both SPMI's the FDA's incentives to expedite review and approval of SPMI's ANDA.

80. The FDA expeditiously approves ANDAs when the generic product that is the subject of the ANDA is not the subject of a patent infringement lawsuit under the Hatch-Waxman Act. For example, when an ANDA filer makes a Paragraph III Certification, certifying that it will only market the drug at issue upon expiration of a patent listed as applying to the drug in the Orange Book, FDA approval typically occurs on the very same day the patent expires.

81. In essentially every instance since the year 2000 involving a brand-name drug coming off patent for which an ANDA filer certified that it would market a generic version of the brand-name drug only upon expiration of the relevant patent (*i.e.* a Paragraph III Certification), the FDA

approved the generic applicant the very day (and in a few instances, within one or two days) of the expiration date of the patent. The ANDAs were consistently timely filed and approved regardless of the magnitude of the brand-name drug's annual sales. Moreover, the FDA approved SPMI's ANDA for generic polyethylene glycol 3350 less than one month after Braintree voluntarily dismissed its patent infringement claim against SPMI. Accordingly, absent Braintree's exclusionary conduct here, the FDA would have promptly and timely approved SPMI's ANDA, permitting generic polyethylene glycol 3350 to enter the market substantially before the actual final approval July 2004, and even before the tentative approval in December 2003.

82. Braintree's scheme to delay the introduction into the U.S. marketplace of any generic version of MiraLax caused Plaintiffs and the Class to pay more than they otherwise would have paid for polyethylene glycol 3350.

83. As noted, generic versions of a brand-name drug are initially priced significantly below the brand-name drug. As a result, upon generic entry, direct purchasers rapidly substitute generic versions of the drug for some or all of their brand purchases. As more generic manufacturers enter the market, prices for generic versions of a drug decrease further because of competition among the generic manufactures. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand-name drug at a reduced price. Consequently, brand-name drug manufactures have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial overcharges from that delay.

ANTITRUST IMPACT UPON PLAINTIFFS AND MEMBERS OF THE CLASS

84. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of MiraLax from Defendant. As a result of Defendant's illegal conduct, members of the

Class were compelled to pay, and did pay, artificially inflated prices for their polyethylene glycol 3350 purchases. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendant, direct purchasers, such as Plaintiffs, would have paid less for polyethylene glycol 3350 by (a) substituting purchases of less-expensive, generic polyethylene glycol 3350 for their purchases of more-expensive branded MiraLax, (b) receiving discounts and/or lowering prices on their remaining branded MiraLax purchases, and (c) purchasing generic polyethylene glycol 3350 at lower prices sooner.

85. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof of trial.

MONOPOLY POWER

86. Prior to the entry of A-rated generic competition, Braintree had monopoly power with respect to its MiraLax brand. Braintree had the power to maintain the price of MiraLax at supracompetitive levels profitably, without losing substantial sales.

87. Prior to generic entry, a small but significant, non-transitory price increase by Braintree to MiraLax would not have caused a significant loss of sales to other products.

88. Prior to generic entry, Braintree sold MiraLax at prices well in excess of marginal costs and enjoyed high profit margins.

89. Prior to generic entry, Braintree exercised the power to exclude competition.

90. To the extent that defining a relevant product market is necessary in this case, the relevant product market is polyethylene glycol 3350 in brand or generic forms.

91. The relevant geographic market is the United States.

92. During and prior to the proposed Class Period, Defendant held a 100% share in the relevant product market in the United States.

CLAIM FOR RELIEF

Violation of Section 2 of the Sherman Antitrust Act

93. Plaintiffs incorporate by reference the preceding allegations.

94. Braintree knowingly and intentionally engaged in a course of conduct that included the procurement of the '183 patent that Braintree knew to be invalid, improperly listing the '183 patent in the Orange Book, and improperly filing and prosecuting objectively baseless patent infringement actions against companies seeking to market competing versions of MiraLax. Braintree's conduct was designed to delay the introduction of generic formulations of MiraLax into the market.

95. Braintree intentionally and wrongfully maintained its monopoly power with respect to MiraLax in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for their polyethylene glycol 3350 purchases.

96. Plaintiffs and members of the Class have been injured in their business or property by Braintree's antitrust violations. Their injury consists of paying higher prices for their polythelene glycol 3350 purchases than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent, flows from that which make Braintree's conduct unlawful, and Plaintiffs are the proper entities to bring a case concerning this conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following:

A. Judgment in its favor and against Defendant for damages representing the overcharges paid by Plaintiff and the other members of the Class, trebled;

B. Pre- and post-judgment interest; and

C. Costs of suit, including reasonable attorneys' fees.

JURY TRIAL DEMANDED

Pursuant to Fed.R.Civ. P. 38(b), Plaintiffs demand a trial by jury of all of the claims asserted in this Complaint so triable.

Dated: March 12, 2007

Respectfully submitted,

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JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
MEIJER, INC. and MEIJER DISTRIBUTION, INC., on behalf of itself and all others similarly situated

(b) County of Residence of First Listed Plaintiff Kent County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number) (302) 656-4433
Rosenthal, Monhait & Goddess, P.A.,
PO Box 1070, Wilmington, DE 19899-1070

DEFENDANTS
BRAINTREE LABORATORIES, INC.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- XX 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	XX 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	☐ 820 Copyrights	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 830 Patent	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 840 Trademark	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health		☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 865 RSI (405(g))	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other			☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)
XX 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): Sherman Act, 15 U.S.C. §2. Civil antitrust action in connection with monopolization
Brief description of cause: of market for the drug polyethylene glycol 3350 (sold as MiraLax)

VII. REQUESTED IN COMPLAINT:
XX CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND $
CHECK YES only if demanded in complaint:
JURY DEMAND: XX Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER 03-477 SLR, 07-142 UNA

DATE 3/12/07

SIGNATURE OF ATTORNEY OF RECORD Jeffrey S. Goddess (No. 630)

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO FORM 85 RECEIPT (REV. 9/04)

United States District Court for the District of Delaware

Civil Action No. 07-143

ACKNOWLEDGMENT OF RECEIPT FOR AO FORM 85

NOTICE OF AVAILABILITY OF A UNITED STATES MAGISTRATE JUDGE TO EXERCISE JURISDICTION

I HEREBY ACKNOWLEDGE RECEIPT OF 1 COPIES OF AO FORM 85.

3-12-07
(Date forms issued)

Lemon Snow
(Signature of Party or their Representative)

Lemon Snow
(Printed name of Party or their Representative)

Note: Completed receipt will be filed in the Civil Action